

U.S. Patent Application Serial No. **10/520,282**
Amendment filed February 11, 2008
Reply to OA dated October 11, 2007

REMARKS

Claims 1-14 are pending in this application. Claim 1 is canceled herein without prejudice or disclaimer, and claims 2-9 are amended. Upon entry of this amendment, claims 2-14 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendments to the claims is as follows. Claims 2, 3, and 5-8 have been amended to be in independent form, incorporating the limitation of canceled base claim 1, and their scope is not changed by this amendment. Claim 4 has been amended to be a method claim, as supported by page 6, line 20, to page 8, line 1, of the specification. Claim 9 has been amended to be in independent form, incorporating the limitation of claim 1, and is further amended to clarify that two of the reaction steps are “a step of reaction one of the separated diastereomers”

Claims 1-14 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. (Office action p. 2)

The Examiner states that: “the phraseologies 'hydrocarbon group', 'chiral secondary hydrocarbon group' and 'chiral group' are not defined in the specification so as to ascertain the structures of the compounds that are included or excluded by the phrases. They are defined by example. However, '[e]xemplification is not an explicit definition.’”

This rejection is respectfully traversed and reconsideration is requested. The terms “hydrocarbon group,” “chiral secondary hydrocarbon group,” and “chiral group” are **well known and well defined in the art**, and therefore **do not have to be defined** in the specification.

The specification is **not** defining these terms by examples. On page 11, line 25, the specification defines group R¹²: “R¹² represents a substituted or unsubstituted hydrocarbon group, ...” However, the listing of examples for group R¹² on page 12, lines 1-4, with the phrase “... **can** be given,” (emphasis added) is simply a listing of possible examples, and is not stated to be a definition of the scope of R¹², or of any of the terms noted by the Examiner.

Claims 1-14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (Office action p. 2)

a) The Examiner states that: “the phraseologies 'hydrocarbon group', 'chiral secondary hydrocarbon group' and 'chiral group' are not defined in the claims so as to ascertain the compounds that are included and/or excluded by the phrases.”

This rejection is respectfully traversed, and reconsideration is requested. The issue here appears to be the same issue as in the rejection under 35 U.S.C. 112, first paragraph, discussed above. As discussed above, the cited terms are well known and well defined in the art.

b) The Examiner states that claim 4 is a duplicate of claim 1.

This rejection is overcome by the amendment to claim 4, amending the claim to be a method claim. Support for this amendment may be found, for example, on page 6, line 20, to page 8, line 1.

c) The Examiner states that claims 6, 9 and 12-14 are confusing because they define R¹²-R¹⁵ as a hydrocarbon group while substituting one for the other.

Reconsideration of this rejection is respectfully requested. Applicant is uncertain what the Examiner means by "substituting one for the other." Applicant submits that the definition of R¹² in the original claims was not indefinite, with the recitation in claim 6 that "R¹² is as defined above" being a reference to the definition of R¹² in base claim 1. However, since claims 6 and 9 are being amended into independent form, the definition from claim 1 that "R¹² represents a substituted or unsubstituted hydrocarbon group, provided that when R¹¹ is a substituted or unsubstituted alkenyl group, R¹² is a chiral group," is incorporated into claims 6 and 9.

Applicant similarly submits that the definitions of R¹³ to R¹⁵ are not indefinite.

d) The Examiner states that claims 7-14 fail to set forth "how" the steps are performed.

This rejection is respectfully traversed, and reconsideration is requested. Applicant is unclear exactly what the Examiner means in stating that the claim does not set forth "how" the steps are performed. Applicant submits that the claim steps are clearly set forth in these claims. Claim

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7 recites the specific step of "processing ... using a simulated moving bed chromatography" Claim 8 recites the step of "distilling" Claim 9 also recites a well defined series of steps (separating; reacting; reacting; separating; reacting).

Claims 1-6 are rejected under 35 U.S.C. §102(a) as being anticipated by Feldman et al., Tetrahed. Lettrs. (1998), Vol 39(19), pp. 2911-2914. (Office action p. 3)

The Examiner states that Feldman discloses compounds 4, 6a, and 6c, which meet the limitations of the present claims.

The rejection of claim 1 is moot in view of the cancellation of claim 1 without prejudice or disclaimer. The rejection of claims 2-6 is respectfully traversed. Claims 2-6 have been amended into independent form, retaining their original scope, by incorporating the limitations of claim 1.

Compound 4 of Feldman is similar to formula (1) in claim 1, but would require R⁴ (or R³) to be phenyl, R¹² to be Bn (n-butyl), and the rest of the substituents R¹-R³ and R¹¹ in formula (1) to be H. However, in the present claims, R³ and R⁴ must be hydrogen or unsubstituted alkyl group, and cannot be phenyl. Therefore, Feldman's compound 4 is **inconsistent** with the structure in claims 2-6.

In addition, all of claims 2-6 require that R¹² is a chiral group. The analogue of position R¹² in Feldman would be the position occupied by the Bn (n-butyl) group. This is not chiralic, and compounds 6a and 6c of Feldman are also inconsistent with the structure in claims 2-6.

Therefore, claims 2-6 are not anticipated by Feldman.

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Claims 1-6 are rejected under 35 U.S.C. §102(a) as being anticipated by Leitich et al., Eur. J. Org. Chem. (2001), Vol. 14, pp. 2707-2718. (Office action p. 4)

The Examiner refers to Leitich's compounds 5a-i.

The rejection of claim 1 is moot in view of the cancellation of claim 1 without prejudice or disclaimer. The rejection of claim 4 is overcome by the amendment to claim 4 to be a method claim. The rejection of claims 2 and 3 is respectfully traversed.

Compound 5a of Leitich is similar in structure to formula (1) in the claims, with groups R¹-R⁴ being similarly labeled in Leitich and in formula (1). However, the analogue of group R¹² would be the TFE (2,2,2-trifluoroethoxide) group in Leitich. The TFE group does **not** meet the limitation on group R¹² in claims 2-3 and 6, all of which require that R¹² is a chiralic group.

Claim 4 has been amended to recite a method for optical resolution characterized by using an optical resolution agent. Leitich discloses addition reactions resulting in the synthesis of compounds including compound 5a, but does not disclose use of these compounds as optical resolution agents in optical resolution methods.

Claims 1-4 are rejected under 35 U.S.C. §102(a) as being anticipated by Semmelhack et al., J. Am. Chem. Soc. (1982), Vol. 104(3), pp. 747-759 (Office action p. 4)

The rejection of claim 1 is moot in view of the cancellation of claim 1 without prejudice or disclaimer. The rejection of claims 2-4 is respectfully traversed.

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The Examiner cites compound 19 of Semmelhack. Compound 19 of Semmelhack is related to formula (1) of the claims, with positions R⁹, R¹⁰ and R¹² being methyl groups, and R⁵ being CO₂Me. However, in claim 4, R⁵ must be a hydrogen atom or a substituted or unsubstituted alkyl group, which is inconsistent with CO₂Me. Moreover, the group at the position corresponding to R¹² in Semmelhack's compound 19 is methyl, while claims 2 and 3 require that this be chiralic.

Claims 1-6 are rejected under 35 U.S.C. §102(a) as being anticipated by Morton et al., J. Am. Chem. Soc. (1970), Vol. 92(14), pp. 4349-4257. (Office action p.4)

The Examiner refers to compound 36 on page 4352.

The rejection of claim 1 is moot in view of the cancellation of claim 1. The rejection of claims 2-3 and 5-6 is respectfully traversed. The rejection of claim 4 is overcome by the amendment to claim 4.

With regard to claims 2 and 3, the group in Morton corresponding to group R¹² is a methyl group, and meet the limitation of claim 2 or 3 that this be a chiralic secondary hydrocarbon group having a crosslinked structure or a chiralic secondary alkyl group substituted with an alkoxycarbonyl group.

With regard to claims 5 and 6, the method of making compound 36 appears to be given on page 4351, right column, 6 text lines from the bottom: "Spiroketone 34 afforded ketal 36 ..." This appears to refer to a photochemical reaction. This method is clearly different from the method disclosed in claim 5 or claim 6.

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With regard to claim 4, Morton does not disclose use of the compound in an optical resolution method.

Claims 1-6 are rejected under 35 U.S.C. §102(a) as being anticipated by Daniewski et al., Bull. Polish Acad. Sci.: Chem., (1989), Vol. 37(7-8), pp. 277-281 (Office action p. 4)

The Examiner cites compounds 10-12 of the reference.

The rejection of claim 1 is moot in view of the cancellation of claim 1. The rejection of claims 2-3 and 5-6 is respectfully traversed. The rejection of claim 4 is overcome by the amendment to claim 4.

The group in the reference corresponding to group R¹² is a methyl group, which does not meet the limitation of claim 2 or 3.

With regard to claim 4, Daniewski does not disclose use of the compound in an optical resolution method.

Regarding process claims 5 and 6, compound 10 in Daniewski (1989) is made from compound 5 (see page 277), which is a lactone, and which is treated with methanol and hydrochloric acid to make compound 10. Compound 5 does not itself correspond to formula (2) in claim 5 or compound (3) in claim 6, and Daniewski (1989) does not disclose a reaction scheme as in claims 5 and 6.

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Claims 1-4 are rejected under 35 U.S.C. §102(a) as being anticipated by Daniewski et al., Synthesis, (1987), Vol. 8, pp. 705-708. (Office action p. 4)

The Examiner refers to compounds 9-11 on page 706.

The rejection of claim 1 is moot in view of the cancellation of claim 1. The rejection of claims 2-3 is respectfully traversed. The rejection of claim 4 is overcome by the amendment to claim 4.

Compound 9 is the same as compound (10) in Daniewski (1989). The groups in the corresponding to group R¹² in the compounds in the reference are methyl groups, and methyl does not meet the limitation on group R¹² in claim 2 or 3.

With regard to claim 4, Daniewski (1987) does not disclose use of the compounds in an optical resolution method.

Claims 1-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over Nemeto, Tetrahed. Lettrs. (1994), Vol. 35(42), pp. 7785-7789. (Office action p. 4)

The Examiner cites compounds 5a-e of Nemeto, and states that “the applicant proviso out [sic] the compounds of Nemeto et al., leaving compounds which are analogous to Nemeto's compounds,” citing *In re Henze*. The Examiner then states that the analogous compounds are *prima facie* obvious, and that the use of an analogous starting material in a well-known process is *prima facie* obvious.

The rejection is moot for claim 1, which has been canceled without prejudice or disclaimer. The rejection of claims 2-14 is respectfully traversed, and reconsideration is requested.

Nemeto's compounds 5a-e differ have an alkenyl group at the position corresponding to R¹¹ in formula (1), but do **not** have a chiral group at position R, corresponding to R¹² in formula (1). All of the present claims would require a chiral group at position R in this case.

Applicant submits that the Examiner's general contention that the compounds of Nemeto are "analogous" to those of claim 1 is in not sufficient to provide a *prima facie* case of obviousness, as the term "analogous" is quite vague. In fact, in order to be consistent with claim 1, Nemeto would have to be **modified to use a chiral group at position R**, and there is no suggestion for this in Nemeto. Nemeto does not discuss use of chiral groups at this position, and all of Nemeto's exemplary groups R are not chiral.

Moreover, Nemeto's reaction scheme from compound 4 to compound 5 is not the same as the process of claim 5, as Nemeto does not start with a compound analogous to that of formula (2).

Claim 7 recites a method for separating a specific diastereomeric mixture. Moreover, Nemeto discloses silica column chromatography of compound 5 (page 7786, line 17), but does not appear to disclose using simulated moving bed chromatography.

Similarly, with regard to claim 8, Nemeto does not appear to disclose distillation of compound 5.

With regard to claims 9-14, there appears to be no disclosure in Nemeto of the use of column 5 for optically resolving alcohols using alcohol exchange with compound 5a, etc. Nemeto

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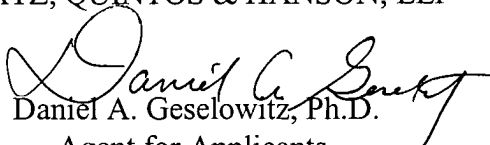
does disclose alcohol exchange, but does not disclose use of chiral alcohols, and there is no suggestion or motivation in the reference to exchange with chiral alcohols, in particular, those which would meet the limitations on group R¹² in the present claims.

If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

In the event that this paper is not timely filed, the applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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Enclosure: Petition for Extension of Time
Amendment Fee Transmittal

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